AUG 24 2006

510(k) Summary for
Dimension Vista™ IGM Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L, M and H

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 061845

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 D-35001 Marburg, Germany
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, Delaware 19714-6101 Attn: Kathleen Dray-Lyons Tel: 781-826-4551 Fax: 781-826-2497
Preparation date:	August 8, 2006

2. **Device Name:** Dimension Vista™ IGM Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Classification: Class II; Class II; Class I
Product Code: CFN; JIX; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. **Identification of the Legally Marketed Device:**

Dade Behring N Antisera to Human IgM – K042735
Dade Behring N Protein Standard SL – K012470
Dade Behring N/T Protein Control SL – K012468

4. **Device Description:**

Dimension Vista™ IGM Flex® reagent cartridge
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is a multi-analyte, liquid human serum based product containing Immunoglobulin A, Immunoglobulin G, and Immunoglobulin M.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are multi-analyte, liquid human serum based products containing Immunoglobulin A, Immunoglobulin G, and Immunoglobulin M.

5. **Device Intended Use:**

Dimension Vista™ IGM Flex® reagent cartridge:
The IgM method is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin M in human serum and heparinized plasma on the Dimension Vista™ System. Measurements of IgM aid in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Dimension Vista™ Protein 1 Calibrator:
Protein 1 Calibrator is an *in vitro* diagnostic product for the calibration of the Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Immunoglobulin M (IGM) methods on the Dimension Vista™ System.

Dimension Vista™ Protein 1 Control L, M and H:
Protein 1 Control L, M and H are assayed intralaboratory quality controls for the assessment of precision and analytical bias in determination of Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Immunoglobulin M (IGM) on the Dimension Vista™ System.

6. **Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista™ IGM Flex® reagent cartridge, Dimension Vista™ Protein 1 Calibrator and Dimension Vista™ Protein 1 Control L, M and H are substantially equivalent to the the Dade Behring N Antisera to Human IgM assay (K042735), N Protein Standard SL (K012470) and N/T Protein Control SL (K012468), respectively. The Dimension Vista™ IGM assay, like Dade Behring N Antisera to Human IGM assay is an *in vitro* diagnostic test for the quantitative measurement of Immunoglobulin M in human serum and plasma by means of particle enhanced immunonephelometry.

7. **Device Performance Characteristics:**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring, Inc.
c/o Ms. Kathleen Dray-Lyons
Regulatory Affairs and Compliance Manager
Glasgow Site
P.O. Box 6101
Newark, DE 19714

AUG 2 4 2006

Re: k061845
Trade/Device Name: Dimension Vista™ Immunoglobulin M Flex® Reagent Cartridge (IgM)
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, E Immunological Test System
Regulatory Class: Class II
Product Code: CFN, JIX, JJY
Dated: June 28, 2006
Received: June 29, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

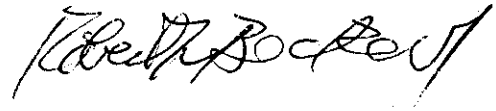
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

510(k) 061845

Device Name: **Dimension Vista™ IGM Flex® reagent cartridge**
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Indications for Use:

Dimension Vista™ IGM Flex® reagent cartridge:
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Dimension Vista™ Protein 1 Calibrator
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Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Immunoglobulin M (IGM) on the Dimension Vista™ System.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Marie M Chan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 061845